

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER: Erez, D. P.

TITLE: CONSTANT FORCE ACTUATOR FOR BLEEDING TIME TESTING DEVICE

Amendment A: REMARKS

Upon entry of the present amendments, previous Claims 1 - 20 have been canceled and new Claims 21 - 39 substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of distinguishing the present invention from the prior art.

In the Office Action, Claims 1 - 20 were rejected under 35 U.S.C. § 102(b) as anticipated by the Schraga patent. Claims 1 - 13 were also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

As an overview to the present reply, Applicant has revised independent Claims 21 and 33 so as to distinguish the present invention from the prior art. Importantly, new independent Claim 21 specifically recites that the "slide frame extends in parallel relation to said bottom surface of said body" and that the slide frame moves "in parallel relation to said bottom surface of said body". Importantly, for the benefit of the Examiner, the bottom surface is particularly defined so that the cutting blade has "a second position extending outwardly of said bottom surface of said body". As such, in relation to the prior art Schraga patent, the bottom surface is certainly the element identified with reference numeral "37", i.e. the surface of the "body" through which the "cutting blade" extends.

The present invention is particularly configured, unlike the Schraga patent, for application

onto a bleeding time testing device. As was stated on page 14, paragraph [0051] of the original specification:

The tripper 10 of the present invention controls the force applied when the bleeding time testing device 12 is used for routine coagulation testing. When the force is controlled, the cutting action of the cutting blade will be more consistent and should minimize variations between operators and techniques employed. The tripper of the present invention has a controlled load which must be overcome in order for the device to activate and perform the incision. The controlled load will ensure that the same force is applied to the incision location (prior to the actual incision) in order to minimize the variations of operator techniques. The tripper 10 of the present invention is positioned over the desired cutting location. The force applied to the actuator button 33 travels directly downwardly at the centerline of the cutting blade position. The slide frame 26 of the actuator will travel a fixed distance so that the razor slide will be released. Once the razor slide is released, the razor slide will travel in a horizontal direction and automatically administer the incision.

Additionally, and furthermore, on pages 14 and 15, paragraph [0052], it is important to note that the present invention removes any pressure variations that may occur by the applications of force during the incision. This was stated as follows:

The present invention controls the applied load at the incision site in order to remove any pressure variations during the incision process. The tripper 10 of the present invention provides tactile feedback to the operator when the actuation has occurred. The slide frame 26 of the tripper 10 remains locked down after actuation so as to ensure that the device cannot be reused. The various safety devices associated with the present invention serve to reduce any occurrences of accidental premature actuation.

Applicant respectfully contends that the prior art Schraga patent simply shows a lancet device used for piercings (as opposed to cutting) the skin in which the lancet is pre-cocked and a button is depressed so as to release the pre-cocked lancet into a piercing orientation and a fired orientation.

This is quite different than the function, use and advantages of the present invention.

Relative to independent Claim 21, Applicant notes the Examiner's "anticipation" rejection. In particular, new independent Claim 21 specifies that the slide frame extends in parallel relation to the bottom surface of the body and that the slide frame moves in parallel relation to the bottom surface of the body. The bottom surface of the body is particularly defined as that surface of the body through which the cutting blade passes.

In the Schraga patent, the bottom surface is that area identified with reference numeral "37". Quite clearly, the slide frame, identified with reference numeral "25", only moves in a direction transverse to the bottom surface of the body. The "slide frame 25" in the Schraga patent moves axially longitudinally through the housing 20 and through the body 82. This is quite different than the orientation of the present invention in which the slide frame extends parallel to the bottom. It is only through the conversion of horizontal motion into the vertical motion of the cutting blade that the present invention achieves its advantage of avoiding pressure variations applied during the application of the present device for the obtaining of a blood sample. In contrast, the Schraga device will still have problems associated with uneven pressures applied to the actuator button 62. When a heavy force is applied to the actuator button 62, the bottom surface 36 may be forced deeper into the skin surface than if light pressure is applied. This may not be very important with the Schraga patent, since the only application of the Schraga patent is for the piercing of the skin, rather than the slicing of the skin with a razor-type cutting blade. However, such a relationship between the slide frame and the bottom surface of the bleeding time testing device is very important so as to assure a proper slicing motion and so that even and consistent cuts are obtained.

Further, in relation to independent Claim 21, Applicant respectfully contends that the piercing

tip 32 is not a "cutting blade". On this basis, Applicant contends that independent Claim 21 is not "anticipated by" the prior art Schraga patent. Applicant has also revised the term "trigger" to the proper term "tripper" so as to overcome the rejection under 35 U.S.C. § 112.

Dependent Claim 22 corresponds to the limitations found in original dependent Claim 2. Since the limitations of previous dependent Claim 3 have been incorporated into independent Claim 21, the previous dependent Claim 3 has been canceled herein. Dependent Claims 23 - 32 correspond, respectively, to the limitations found in previous dependent Claims 4 - 13. In particular, with respect to the dependent claims, Applicant has revised dependent Claim 24 (from the original dependent Claim 5) so as to indicate that the actuator button has a pin extending inwardly therefrom "in parallel relation to said bottom surface of said body". Additionally, it was indicated that the inverted U-shaped slot" is formed "on a side" of the slide frame. Relative to the Schraga patent, the "inverted U-shaped slot is actually located between the sides of the slide frame and not on a side. On this basis, Applicant contends that dependent Claim 24 is not anticipated by the prior art Schraga patent.

Relative to dependent Claim 25 (reflect the limitations of pervious dependent Claim 6), Applicant respectfully disagrees with the Examiner's anticipation rejection. In particular, dependent Claim 25 recites the limitations of "said pin received in and slidable along said slot of said housing". To the extent that the Examiner has identified the pin as the item marked with reference numeral "64" in the Schraga patent, it is, in no way, slidable along the slot of the housing. It does move "interior" of the housing, but is not slidable in any "slotted" area of the housing.

Relative to dependent Claim 28 (reflecting the limitations of previous dependent Claim 9), the prior art Schraga patent does not show the "slide frame extending through and between said pair of legs". Quite clearly, the legs (also identified with the reference numeral 64 in the Schraga patent)

would extend through the slide frame. The slide frame in the Schraga patent, in no way, extends through and between these pair of legs.

Applicant has revised dependent Claim 29 (reflecting the limitations of previous dependent Claim 10) so as to indicate that the spring is interposed between a surface of the housing and "in contact with" an underside of the top surface of the actuator button. The spring 44 in the Schraga patent, in no way, contacts the underside of the top surface of the actuator button 62. On this basis, Applicant contends that dependent Claim 29 is not anticipated by the Schraga patent.

New independent Claim 33 specially recites that the actuator button "extends transverse the slide frame". Additionally, it is indicated that the slide frame "moves transversely" to an axis of movement of the actuator button. Applicant respectfully contends that new independent Claim 33 is not anticipated by the Schraga patent. The Schraga patent has a "slide frame 25" that moves in axial alignment with the movement of the actuator button. It does not move "transversely" to the axis of movement of the actuator button. Additionally, the actuator button is actually aligned with the slide frame and not "transverse thereto". On this basis, Applicant contends that independent Claim 33 is not anticipated by the prior art Schraga patent.

Dependent Claims 34 - 39 reflect the limitations, respectively, of previous dependent Claims 15 - 20. Dependent Claim 36 (reflecting the limitations of previous dependent Claim 18) indicates that the spring "contacts" an underside of the top surface of the actuator button. This is quite clearly not shown in the Schraga patent. Relative to dependent Claim 39 (reflecting the limitations of dependent Claim 20), Applicant respectfully contends that there is no indication in the Schraga patent that each of the first and second sides of the slide frame has "inverted U-shaped slots formed therein". There appears to be only a single inverted U-shaped slot in the Schraga patent. This slot

appears to be located between the sides of the slide frame rather than on each of the sides. On this basis, Applicant contends that independent Claim 39 is not anticipated by the Schraga patent.

Based upon the foregoing analysis, Applicant contends that independent Claims 21 and 33 are now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

<u>October 26, 2006</u>	<u>/Andrew W. Chu/</u>
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